

REMARKS

Claims 1-10 are pending in the application. Claim 4 was amended in order to compact and expedite prosecution and the amendment was made solely to reply to this office action. Applicants hereby reserve the right to pursue the canceled subject matter in one or more continuation or divisional applications. No new matter was added by virtue of these amendments and entry is respectfully requested.

During a telephonic conversation, with the Examiner, Applicants elected, with traverse, Group I, claims 1-6, drawn to a method of detecting a neuronal injury in a subject, classified in class 435, subclass 7.1+, for example. Applicants submit, that a search of the method detecting a neuronal injury in a subject would yield the same results as a search for a kit that is used for detecting a neuronal injury in a subject. As such, this would not be an undue burden on the Patent Office. Applicants respectfully request that lifting the restriction requirement and prosecuting Groups I and II would result in a significant savings of time and resources for both the Patent Office and Applicants.

The elected claims set forth, herein, are merely to comply with the Restriction Requirement and is not to be construed as surrender of any subject matter in the instant application. Applicants hereby reserve the right to pursue the subject matter of the canceled claims in one or more divisional patent applications. Based on the above election, Applicants request removal of the restriction requirement and substantive examination of all elected claims.

Claim Rejections Under 35 U.S.C. § 102

Claims 1-6 are rejected under 35 U.S.C. § 102(b) as being anticipated by Hu *et al.* ("Hu").

Applicants respectfully traverse.

Hu is directed to bienzyme substrate-recycle ELISA using samples from lumbar cerebrospinal fluid. Hu neither teaches nor discloses that the NF-H leaks into the other bodily fluids such as blood, serum and other fluids as taught by Applicants. Applicants invention is directed in part to a method of detecting neuronal injury in a subject, the method comprising the steps of:

- (a) providing a biological sample derived from the subject;
- (b) detecting the presence or amount of at least one neurofilament derived protein or peptide (NFDp) in the sample;
- (c) correlating the presence or amount of the NFDp in the sample with the neuronal injury. The biological sample is a fluid selected from the group consisting of blood, serum, plasma, CSF or other bodily fluids. In addition, Applicants have amended claim 4 to expedite prosecution and withdrawn the term "CSF." Applicants reserve the right to prosecute the withdrawn subject matter in one or more divisional or continuation applications.

Applicants submit that Hu fails to teach each and every claim limitation and as such fails as a reference.

In view thereof, Applicants respectfully request reconsideration and withdrawal of the instant rejection.

Claims 1-2 and 5 are rejected under 35 U.S.C. § 102(b) as being anticipated by Meller et al. ("Meller").

Applicants respectfully traverse.

Meller is directed to immunohistochemistry of a brain tissue. Meller neither teaches nor discloses that the NF-H leaks into the CSF and serum and other fluids as taught by Applicants. Applicants invention is directed in part to a method of detecting neuronal injury in a subject, the method comprising the steps of:

- (a) providing a biological sample derived from the subject;
- (b) detecting the presence or amount of at least one neurofilament derived protein or peptide (NFDP) in the sample;
- (c) correlating the presence or amount of the NFDP in the sample with the neuronal injury. The biological sample is a fluid selected from the group consisting of blood, serum, plasma, CSF or other bodily fluids.

Applicants submit that Meller fails to teach each and every claim limitation and as such fails as a reference.

In view thereof, Applicants respectfully request reconsideration and withdrawal of the instant rejection.

Claim Rejections Under 35 U.S.C. § 103

Claims 1-6 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Meller et al., ("Meller") in view of Hu et al. ("Hu").

Applicants respectfully traverse.

Meller relates to brain tissue samples and does not relate to using ELISA or CSF to detect neurofilament proteins and requires brain surgery or death of a patient in order to identify any neurofilaments. Hu discusses an bienzyme substrate-recycle ELISA using samples from lumbar cerebrospinal fluid. Hu neither teaches nor discloses that the NF-H leaks into the other bodily fluids such as blood, serum and other fluids as taught by Applicants. It would not have been obvious to one of ordinary skill in the art to combine Meller and Hu and arrive at the instant invention. Both procedures need invasive methods to obtain a sample. Furthermore, it is, not obvious to one of skill in the art that neurofilaments could be detected in other bodily fluids. Applicants submit, that the instant invention is novel and unobvious to one of skill in the art.

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In view thereof, Applicants respectfully request reconsideration and withdrawal of the instant rejection.

CONCLUSION

Applicants respectfully request entry of the foregoing remarks and reconsideration and withdrawal of all rejections. It is respectfully submitted that this application with claims 1-18 define patentable subject matter and is in condition for allowance. Accordingly, Applicant respectfully requests allowance of these claims.

Applicants have made every effort to present claims which distinguish over the cited art, and it is believed that all claims are now in condition for allowance. However, Applicants request that the Examiner call the undersigned (direct line 561-671-3666) if anything further is required by the Examiner prior to issuance of a Notice of Allowance for all claims.

Although, Applicants believe that no further extensions of time are required with submission of this paper, Applicants request that this submission also be considered as a petition for any further extensions of time if necessary. The Commissioner for Patents and Trademarks is hereby authorized to charge the amount due for any retroactive extensions of time and any deficiency in any fees due with the filing of this paper or credit any overpayment in any fees paid on the filing or during prosecution of this application to Deposit Account No. 50-0951.

Respectfully submitted,
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